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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,258	09/16/2003	Jose Engelmayer	H0-P02652US1	2875

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,258	ENGELMAYER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 15-51 are pending.

Applicants' amendment filed March 30, 2007 is acknowledged. Applicant's response has been fully considered. Claims 16, 26, 30, 31, 33 and 50-51 have been amended. Therefore, claims 15-51 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 26 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 7 in the amendment filed March 30, 2007.

Withdrawn Claim Rejections -- 35 USC § 102

3. The previous rejection of claims 15-19, 21-24, 26, 27, 29 and 31-51 under 35 U.S.C. 102(b) as anticipated by Ando *et al.* (U. S. Patent 5,576,299), is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 7-8 in the amendment filed March 30, 2007.

Withdrawn Claim Rejections -- 35 USC § 103

4. The previous rejection of claims 16, 17, 21-23, 26, 28 and 30-47 under 35 U.S.C. 103(a) as being unpatentable over Kruzel *et al.* (US Patent 6,066,469), is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 8-9 in the amendment filed March 30, 2007.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 16-51 are directed to a method of treating a wound, other than burn wounds, oral wounds, ophthalmic wounds or gastric or duodenal ulcers, comprising the step of administering to a subject, other than by buccal administration, or administering topically, a therapeutically effective amount of a lactoferrin composition. While the specification discloses the present invention is a method of treating a wound comprising the step of administering to a subject a lactoferrin composition in an amount sufficient to provide an improvement in the wound (paragraph [0017]), exemplary wounds that can be treated include skin wounds, bone wounds, internal wounds gastrointestinal wounds, oral wounds, ophthalmic wounds, surgical wounds, or any combination thereof (paragraph [0019]), and oral administration used includes oral, buccal, enteral or intragastric administration, the specification does not indicate that the use of a lactoferrin composition in the treatment of a wound, other than burn wounds, oral wounds, ophthalmic wounds or gastric or duodenal ulcers by administering a lactoferrin other than buccal administration. The lack of description of treating wounds other than burn wounds, oral wounds, ophthalmic wounds or gastric or duodenal ulcers by administering a lactoferrin composition other than by buccal administration, and the lack of representative species as

encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ando *et al.* (U. S. Patent 5,576,299, published November 19, 1996) as evidenced by Engelmayer *et al.* (US 2004/0142037 A1).

Ando *et al.* disclose a formulation containing lactoferrin or transferrin is used for treating opportunistic infectious diseases under immunodeficient condition caused by Lentiviral infection (column 2, lines 10-21), e.g., granules containing human apolactoferrin (350 mg/day) were given to HIV positive patients with recurrent stomatitis and gingivitis once daily for 4 weeks, where the patients have aphthae or ulcers on the mucosa of the oral cavity and lip, and the inflammation in the oral cavity and pain was ameliorated after the treatment (Example 2) and feline immunodecificiency virus (FIV)-positive cats were treated with bovine native lactoferrin (20 mg/kg daily), which was dissolved in distilled water, and the solution was sprayed over ulcers and aphthae in the oral cavity, the treatment lasted 7 days to several months, and the appetite increased and the pain ameliorated after the lactoferrin treatment (Example 4). The reference

also teaches the pharmaceutical composition may contain the active compound (i.e., transferrin/lactoferrin) together with a solid or liquid pharmaceutically acceptable carrier, and suitable excipients such as sugar, gelatin (claims 15), magnesium carbonate or magnesium stearate may be employed (column 4, line 21-column 5, line 3). Although Ando *et al.* do not specifically disclose the viscosity of gelatin, the gelatin is one of the polymers to provide a viscosity in the range of about 1 to about 12,000,000 cP at room temperature as evidenced by Engelmayer *et al.* (see paragraphs [0012] and [0013]). Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that a lactoferrin composition comprising gelatin having a viscosity in the range of about 1-12,000,000 cP at room temperature is used for treating wounds because a composition comprising lactoferrin and gelatin can be prepared as a pharmaceutical composition for the treatment as suggested by Ando *et al.*

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 15-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-14, 16, 18-22 and 35-38 of copending Application No. 10/733,621 (based on the amended claims filed September 26,

2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-51 in the instant application disclose a method of treating a wound, or enhancing the local or systemic immune system in a subject suffering from a wound by administering to the subject an effective amount of a lactoferrin composition comprising a lactoferrin and a pharmaceutically acceptable carrier. This is an obvious variation in view of claims 1, 3-14, 16, 18-22 and 35-38 in the copending application which disclose a method of treating a subject suffering from pain comprising the step of administering to the subject an effective amount of a lactoferrin composition, wherein the pain is associated with cancer or surgery; and the specification discloses the composition comprising a lactoferrin and a pharmaceutically acceptable carrier can be a gel composition comprising Carbopol. Both the claims of instant application and the claims of the copending application are directed to a method of treating wound or a patient having a pain from surgery by administering a lactoferrin composition, where a patient having a pain from surgery would be expected to have a wound. Thus, claims 15-51 in present application and claims 1, 3-14, 16, 18-22 and 35-38 in the copending application are obvious variations of a method of treating wound by administering a lactoferrin composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 16-22, 26-30 and 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 14, 17-19, 26-32 and 38-40 of copending Application No. 10/728,521 (based on the amended claims filed September 26, 2006). Although the conflicting claims are not identical, they are not patentably

distinct from each other because claims 16-22, 26-30 and 50-51 disclose a method of treating a wound other than ophthalmic wounds, or enhancing the local or systemic immune system in a subject suffering from a wound by administering to the subject an effective amount of a lactoferrin composition; and the specification indicates a lactoferrin composition can have an N-terminal lactoferrin variant such as N-terminal glycine deleted or substituted or a deletion, substitution, or combination thereof, of from 1 to 16 N-terminal amino acid residues and the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin (paragraphs [0009] and [0048]), and the lactoferrin composition can decrease bacterial infection of the wound (paragraphs [0102]). This is an obvious variation in view of claims 1, 7, 14, 17-19, 26-32 and 38-40 in the copending application which disclose a method of treating bacteremia or sepsis, enhancing a mucosal response in the gastrointestinal tract or decreasing mortality of a subject having bacteremia, comprising the step of administering orally to a subject an effective amount of a lactoferrin composition comprising at least 1% to at least 50% w/w of an N-terminal lactoferrin variant to provide an improvement in the bacteremia of said subject, wherein the N-terminal lactoferrin variant has a deletion, substitution, or combination thereof, of from 1 to 16 N-terminal amino acid residues and wherein the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin; and the specification indicates sepsis or bacteremia may originate anywhere in the body such as surgical wounds or decubitus ulcers (paragraphs [0003] and [0082]). Both the claims of instant application and the claims of the copending application are directed to a method of treating bacteremia or sepsis, or treating wounds such as wounds causing bacteremia or sepsis by administering a lactoferrin composition comprising an N-terminal lactoferrin variant. Thus, claims 16-22, 26-30 and 50-51 in present application and

claims 1, 7, 14, 17-19, 26-32 and 38-40 in the copending application are obvious variations of a method of treating bacteremia or sepsis, or wounds causing bacteremia or sepsis by administering a lactoferrin composition comprising an N-terminal lactoferrin variant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate the provisional rejections should be withdrawn and the instant application allowed to issue when the provisional rejections are the only rejections remaining (page 9 of the response).

Applicants' response has been considered, since there are other outstanding rejections in this office Action. Thus, the provisional obviousness-type double patenting rejection is maintained.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
June 2, 2007